

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	
)	(Subcategory Docket: 06-11337)
THIS DOCUMENT RELATES TO)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Judge Patti B. Saris
<i>Inc. v. Abbott Laboratories, Inc.,</i>)	
No. 07-CV-11618-PBS)	Magistrate Judge Marianne B. Bowler

**ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT OF
ITS MOTION FOR SUMMARY JUDGMENT**

Dated: August 28, 2009

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INTRODUCTION

Ven-A-Care of the Florida Keys, Inc. (“Ven-A-Care”) brings this False Claims Act (“FCA”) action alleging that Abbott Laboratories Inc. (“Abbott”) fraudulently reported prices of several of Abbott’s generic oral Erythromycin (“Ery”) drugs. The United States determined not to intervene in this action. Ven-A-Care gave up its business as a home infusion pharmacy in the mid-1990s, and has been a full-time FCA relator since then. It is undisputed that Ven-A-Care never purchased or dispensed, or received Medicaid payments for, any of the Erys. Instead, Ven-A-Care came by its knowledge of the allegations in this case by reviewing public price compendia such as Redbook and wholesaler price lists – the same compendia and price lists to which thousands of other pharmacies and other providers had ready access. Ven-A-Care did not file its initial claims on the Ery drugs until 2001, by which time (as this Court has recognized) there was already a “perfect storm” of knowledge of the price spreads about which Ven-A-Care complains.

Ven-A-Care filed its first complaint alleging pricing fraud against Abbott in 1995. Ven-A-Care’s original 2001 complaint alleging price fraud with respect to Ery drugs was limited to Abbott’s reporting of Wholesale Acquisition Costs (“WACs”) for six Ery drugs (thirteen National Drug Codes (“NDCs”)) and the impact of that reporting on the eight state Medicaid programs that allegedly used WACs to calculate payments to pharmacies. After amending the complaint twice to add additional Ery drugs, in 2005, Ven-A-Care drastically altered its case by amending its complaint (still under seal) and expanding its claims to AWP and all states. By the time Ven-A-Care filed an unsealed complaint in 2007 – six years after it had originally made its claims about Erys and twelve years after it had filed its first AWP complaint – it had also expanded its claims to seventeen Ery drugs (forty-three NDCs).

Ven-A-Care’s complaint has two counts under the FCA: Count I for an alleged violation

of 31 U.S.C. §3729(a)(1) and Count II for an alleged violation of 31 U.S.C. § 3729(a)(2). The essence of Ven-A-Care's complaint is that Abbott "used the public fisc as a marketing tool, actively promoting government-funded 'spreads' between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. These efforts allowed Abbott to increase its profits by boosting sales for its drugs" and that this "marketing the spread" violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b). Count I of Ven-A-Care's complaint (for causing to be presented false or fraudulent claims under 31 U.S.C. §3729(a)(1)) is predicated on this alleged violation of the anti-kickback statute. Ven-A-Care's allegations for this count are legally deficient, and there is no evidence of Abbott actively marketing the spread on the Ery drugs or boosting its sales due to such an effort.

In addition to deficiencies in the liability claims, Ven-A-Care's damages calculations are insufficient to withstand summary judgment. Ven-A-Care alleges that the price spreads resulted in state Medicaid programs "over-paying" pharmacies for the Erys by approximately \$15.5 million dollars from 1994 through 2007. Ven-A-Care's calculations, however, include Medicaid claims for which there is no evidence that the state's payment was based on a price that Abbott reported. In fact, the undisputed evidence shows that Federal Upper Limit ("FULs"), state Maximum Allowable Costs ("MACs"), and even calculations of "estimated acquisition cost" ("EAC") were in many cases not based on any price that Abbott had reported. Ven-A-Care compounds this error by calculating damages for alleged Medicaid claims that were derived, not from actual evidence, but from the expert's unscientific and wholly unsupported extrapolations. Finally, Ven-A-Care also includes claims relating to Texas and California Medicaid that have been settled and released.

As demonstrated below, Abbott is entitled to summary judgment as a matter of law for

the following reasons.¹

First, the FCA's six-year statute of limitations precludes Ven-A-Care's efforts repeatedly to expand its case, years after filing its initial claims, from a modest one involving WAC reporting for six formulations of Ery (13 NDCs) and eight states to a national case involving AWP for seventeen formulations of Ery (43 NDCs) and all Medicaid states.

Second, there can be no causation under the FCA after Ven-A-Care fully apprised the Government of the Ery claims in 2001, which is also the date on which this Court has found there existed a "perfect storm" of knowledge about large spreads between published prices, such as AWP and WAC, and transactional prices. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 40 (D. Mass. 2007).

Third, Count I fails because Ven-A-Care has no evidence that Abbott violated the anti-kickback statute, the predicate for Ven-A-Care's claim that Abbott "caused" a false claim to be presented.

Fourth, Ven-A-Care has improperly requested damages for Medicaid claims even though Ven-A-Care has no evidence that the claims were paid based on a price reported by Abbott.

Fifth, Ven-A-Care's damages expert has improperly extrapolated damages for claims for which Ven-A-Care has no evidence.

Sixth, Ven-A-Care improperly seeks damages for claims that have been settled and released.

¹ Abbott has also filed a motion to dismiss for lack of subject-matter jurisdiction based on the FCA's public disclosure bar. Because Abbott is challenging this Court's jurisdiction, Abbott respectfully suggests that the Court should adjudicate the motion to dismiss first. *See Deniz v. Muni of Guaynabo*, 285 F.3d 142, 149-150 (1st Cir. 2002) ("After all, if the court lacks subject matter jurisdiction, assessment of the merits becomes a matter of purely academic interest."); *Ostroff v. Florida Dep't of Health & Rehabilitative Services, et al.* 554 F. Supp. 347, 350 n.1 (M.D. Fla. 1983) ("The Court is obligated to give initial consideration to [] jurisdictional questions, since if it must dismiss for lack of subject matter jurisdiction all other matters become moot and need not be determined.").

FACTS

There is no genuine issue as to the following material facts, all of which are supported by Abbott's Rule 56.1 Statement of Facts ("SOF"), which is being filed with this motion.

A. Ven-A-Care's Under-Seal Complaints And Current Complaint Addressing Ery Drugs.

Ven-A-Care filed a suit under seal in 1995 against various pharmaceutical manufacturers, including Abbott, alleging that price spreads amounted to fraud against the Medicaid and Medicare programs and violated the FCA (the "DOJ case"). (SOF ¶ 2.) Ven-A-Care alleged that Abbott violated the FCA by reporting inflated prices for several infusion and injectable pharmaceutical products that were produced by Abbott's Hospital Products Division ("HPD"). (*Id.* ¶ 3.) Ven-A-Care amended the under-seal complaint against Abbott several times, eventually adding the allegation that Abbott marketed the spreads to increase its market share of the drugs at issue and in 2002 allegations regarding Abbott's Ery drugs (produced by Abbott's Pharmacy Products Division ("PPD")). (*Id.* ¶¶ 4-5.) For the next eleven years, the United State's Department of Justice engaged in broad discovery of Abbott's sales and marketing practices, before finally deciding to intervene in the complaint against Abbott in 2006 with respect to four of Abbott's HPD products – Vancomycin, sodium chloride, sterile water, and dextrose. (*Id.* ¶ 6.) This action is now unsealed and pending before this Court. In the early-to-mid-2000s, Ven-A-Care, with individual states including Texas and California, also unsealed similar other actions against Abbott, seeking the state and federal portions of damages relating to alleged Medicaid price reporting fraud. (*Id.* ¶¶ 130-31.)

On February 15, 2001, six years after filing its AWP-based under-seal complaint in Florida, Ven-A-Care amended another under-seal complaint in the United States District Court for the District of Massachusetts that Ven-A-Care had filed on April 10, 2000 against other drug

manufacturers (No. 00-CV-10698, the “Massachusetts case”). Ven-A-Care added Abbott as a defendant and set forth allegations about six Ery drugs (thirteen NDCs). (SOF ¶¶ 7-8.) The amended complaint alleged that Abbott and the other named drug manufacturers “falsely represented the prices that they charged wholesalers for certain of their generic prescription drugs.” (*Id.* ¶ 9.) The 2001 amended complaint further alleged that this “wholesaler information” was used to determine the Wholesaler Acquisition Cost (‘WAC’) for the specified drugs, which a few state Medicaid programs, in turn, relied upon for setting the amount that they would reimburse a pharmacy. (*Id.* ¶ 10.) This complaint identified eight states (Alabama, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas) as “WAC STATES” that utilized Abbott’s allegedly false WAC information. (*Id.* ¶¶ 10-11.) Ven-A-Care made no allegations with respect to published AWP’s. (*Id.* ¶ 12.)

Prior to filing this complaint, Ven-A-Care had provided to the Government a 31 U.S.C. § 3730(b)(2) disclosure and a copy of the Econolink pricing database (*see infra*) that Ven-A-Care used then and later to look up the prices of Ery drugs to compare to the compendia prices. (SOF ¶¶ 49-51.)

Ven-A-Care filed a second amended complaint in the Massachusetts case on February 1, 2002, which added an allegation that Abbott “[t]hrough its direct prices” (i.e., list prices) also knowingly defrauded California Medicaid. (SOF ¶ 13.)

On February 15, 2005, in its third amended complaint, Ven-A-Care dramatically expanded its theory of fraud by alleging that Abbott caused the publication of false AWP’s in addition to false WACs and direct prices. (SOF ¶ 15.) This additional allegation expanded the case to all forty-nine state Medicaid programs. This amendment also added five more formulations of Ery (thirteen NDCs). (*Id.* ¶¶ 16-17.)

On August 30, 2007, after the United States declined to intervene, Ven-A-Care severed its claims against Abbott and filed the current complaint (Case No. 07-CV-11618, the “Complaint”), which is the subject of this motion for summary judgment. (SOF ¶ 19.) With this Complaint, Ven-A-Care added seventeen more Ery NDCs, bringing the total number of Ery NDCs to forty-three. (*Id.* ¶ 20.)

The Complaint alleges two causes of action under the FCA. Count I alleges that “Abbott knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States” by “knowingly using the spread [between reported prices and providers’ actual acquisition costs] as an unlawful inducement in violation of the federal anti-kickback statute” in violation of 31 U.S.C. § 3729(a)(1). (SOF ¶¶ 21-22.) Count II alleges that “Abbott knowingly made, used, or caused to be made or used, false records or statements to cause false or fraudulent claims to be paid or approved by the United States” in violation of 31 U.S.C. § 3729(a)(2). (*Id.* ¶ 22.)

Ven-A-Care makes these allegations based only on its review of public price compendia and wholesaler price list, mainly Mckesson’s Econolink database. (SOF ¶¶ 42-49.) Ven-a-Care has never submitted a Medicaid claim on any Ery drug, and has not submitted a claim on any drug since 1998. (*Id.* ¶¶ 42, 46.) Ven-A-Care has absolutely no knowledge of Abbott marketing any spread on any Ery drug. (*Id.* ¶¶ 42-48.)

B. Public Disclosures About Ery.

Throughout the 1980s and 1990s, public disclosures about price spreads continued and included specific disclosures relating to Abbott and the Erys. For example, in 1984 the HHS-OIG issued a report titled “Medicaid—Limitation on payment for drugs.” (SOF ¶ 25.) The report noted that “AWP means non-discounted list price” and that “[p]harmacies purchase drugs at prices that are discounted significantly below AWP or list price.” (*Id.*) The report analyzed

the differences between AWP and pharmacy acquisition costs for a select number of drugs, including EES 400[®], an Abbott trademarked drug at issue in this case. (*Id.*) The report found that the 70th percentile of the audited prices for EES 400[®] was \$16.49 while the published AWP was \$21.95 – a spread of 33%. (*Id.*) The report further found that the median price paid for EES 400[®] in Massachusetts was \$14.06 – a spread of 56% between the median price and the AWP.² (*Id.*)

In July 1992, the Energy and Commerce Committee of the U.S. House of Representatives held a hearing concerning proposed bills to establish limits on certain drug prices. (SOF ¶ 29.) As part of that hearing, price lists showing the discrepancies between AWP and contract prices available to certain providers were introduced into the public record. (*Id.*) Several versions of Abbott's Erys at issue in this case were on that list, including EES 400[®] TABs, EES[®] 200 liquid, EES 400[®] liquid, Ery-TAB[®] 250 mg tabs, Ery-TAB[®] 333 mg, and Ery-TAB[®] 500 mg. (*Id.* ¶ 30) The price lists show discounts for these drugs ranging from AWP-56% to AWP-86% (spreads of 127% to 614%). (*Id.*)

In August 1997, the HHSC's office of Inspector General issued a comprehensive report that concluded that pharmacies pay an average of 42.5% less than AWP for generic drugs, such as Abbott's Ery drugs, dispensed to Medicaid beneficiaries. (SOF ¶ 31.) This report publicly disclosed that generic drugs, on average, had spreads of approximately 74% which is similar to the spreads that Ven-A-Care alleges in this case. While the report does not name any specific drug, there can be no doubt that the report included oral, patient administrated, generic drugs such as the Erys, and OIG work papers created in connection with the report specifically show

² The spreads represented in Ven-A-Care's Complaint are in effect exaggerated by 100%. For example, based on Ven-A-Care's method of calculating spread in the Complaint's Exhibit A, even if a drug's AWP is only 5% more than the "relator's cost," Ven-A-Care would claim that drug has a 105% spread. For consistency and to enable valid comparisons, this brief will utilize a proper calculation of spread ((AWP-AAC)/AAC or (AWP/AAC)-1.0).

that the report included Abbott's Ery-TAB.[®] (*Id.*) (For other examples of public disclosures about Erys, see *id.* ¶¶ 26 - 41.)

Indeed, by 2001, as this Court has recognized in another AWP case, "there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ('OIG'). In addition, the press began to report on the rampant abuse of the AWP system." See *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 40. There can be no doubt that by 2001, armed with these public disclosures, Average Manufacturer's Prices ("AMPs") that Abbott was reporting to CMS and Ven-A-Care's complaint and Section 3730(b)(2) disclosure, the Government fully knew about the Ery price spreads and the alleged fraud.

C. The Ery Drugs.

As a matter of course, Abbott PPD reported to the pricing compendia a WAC and a list price at the launch of a product and whenever the product's WAC or list price changed. (SOF ¶ 53.) Abbott PPD reported WAC and list price changes for the Ery drugs at issue five times during the claimed relevant period. (*Id.* ¶ 54.) To Abbott, the WAC represented the price charged, prior to applying any discount or rebate, to wholesalers and other customers that purchased a case or more of a product. (*Id.* ¶ 55.) To Abbott, the list price represented the price charged to any non-contract customer that purchased less than a case of a product. (*Id.* ¶ 56.)³ Abbott had sales of the Ery drugs at both its published WACs and list prices. (*Id.* ¶ 60.) They both, therefore, were real transaction prices.

³ Although it is not material to this motion, it is noteworthy that Abbott's interpretations of the pricing terms are well supported. By its plain meaning, "list price" refers to "a basic price of an item as published in a catalog, price list or advertisement before any discounts are taken." (SOF ¶ 58, *citing* Merriam-Webster's online dictionary at <http://www.merriam-webster.com/dictionary/list%20price> (last visited on July 25, 2009).) WAC is understood in the industry to represent a type of list price to wholesalers. (*Id.* ¶ 59.) Congress explicitly recognized this definition of WAC when it passed the Medicare Modernization Act of 2003. (*Id.*) There are plenty of other sources that defined WAC, as Abbott did, as an undiscounted list price. (*Id.*)

Every Abbott PPD employee deposed on this issue testified that he or she thought that Abbott was reporting the prices that the pricing compendia wanted and in accordance with Abbott's use and understanding of those terms. (SOF ¶¶ 57, 62-64.) For example, Joseph Fiske, who was the Director of Pricing and Planning, testified:

The information that we reported to the data agencies was our WAC and our list price. Any changes to our WAC and list price, we did so in good faith with the expectation that that was the information we should be providing. Nobody told us to do anything differently than that, including Kay Morgan who certainly had the opportunity because she knew what our practices were.

(*Id.* ¶ 64.) Kay Morgan worked at Abbott from 1975 to 1999 and then went to First DataBank as Manager of Editorial Services where she was responsible for the pricing information First DataBank published until 2005. (*Id.* ¶ 65.) As such, she was familiar with both Abbott's pricing practices described above and the information that First DataBank intended to obtain from manufacturers. (*Id.*) Furthermore, April Gerzel, the only Abbott PPD employee whom Ven-A-Care deposed in this case who had direct communications with the pricing compendia, testified that she understood that the pricing compendia were requesting that Abbott report its WACs and list prices. (*Id.* ¶ 64.)

There is no evidence that Abbott made any attempt to market the alleged price spreads on the Erys. (SOF ¶ 66.) All deposed Abbott employees unequivocally denied marketing the spread or setting prices in order to do so. (*Id.*) Finding no evidence to support its allegation that Abbott "actively promot[ed] [the] spreads" "as a marketing tool," Ven-a-Care relies on an argument that the spreads marketed themselves. That theory does not even make sense with respect to the Erys because, among other reasons, Medicaid payments for the Erys typically were capped by FULs and MACs. (*Id.* ¶¶ 71-72, 87-88.) Thus, a pharmacy could not increase its

Medicaid payment by submitting a claim for an erythromycin with a higher AWP. (*Id.*) In other words, marketing the spread would have been futile.

D. Medicaid Payments For The Ery Drugs.

In recognition of the disparity between published prices and other transactional prices for generic drugs, the Secretary of Health and Human Services established the FUL program in 1987. *See* 52 Fed. Reg. 28648, 28653 (July 31, 1987). The Secretary established the FUL to allow “the Federal and State governments to take advantage of savings that are currently available in the marketplace for multiple source drugs . . . [while] maintain[ing] State flexibility in the administration of the Medicaid program.” (SOF ¶¶ 67-68.) According to regulations, CMS was to establish FULs on individual drugs by computing an amount equal to 150 percent of the lowest published price for all generically equivalent versions of the drug. (*Id.* ¶ 70.) Additionally, individual state Medicaid programs established even lower MACs for many generic drugs using a variety of information and formulae. (*Id.* ¶ 88.)

During the alleged relevant period, there were FULs and MACs capping Medicaid payments for the Ery drugs, among the other multisource, oral erythromycins. (SOF ¶¶ 71, 88.) Although federal regulation instructed CMS to set FULs at 150 percent of the published price for the least costly generic equivalent (*id.* ¶ 70), CMS sometimes disregarded published prices when setting FULs, and set higher FULs in response to feedback from the pharmacy community or to assure Medicaid patients’ access to pharmaceuticals. (*Id.* ¶¶ 73-78.) Similarly, states Medicaid program often set MACs based on information other than published prices, including: invoices provided by pharmacies; direct surveys of pharmacies; and review of wholesaler catalogs and price lists. (*Id.* ¶ 89.) Many states considered pharmacies’ input and policy considerations, such as access issues, when setting MACs and the formulas to calculate EACs. (*Id.* ¶ 90-92.) The

bottom line is that published prices about which Ven-A-Care complains often had nothing to do with the eventual Medicaid payments on the Ery drugs.

E. Ven-A-Care's Damages Computation.

The Complaint seeks damages from January 1, 1994 through “the present.” Ven-A-Care’s damages expert, Professor Mark G. Duggan, has calculated an approximate \$15.5 million “difference” between what he has characterized as (1) what the federal government reimbursed for the Erys dispensed to Medicaid recipients first quarter of 1994 through the first quarter of 2008 and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used. (SOF ¶ 99.)

Duggan’s calculation is fatally flawed for several reasons, two of which warrant summary judgment on Ven-A-Care’s damages claim.⁴ First, Duggan’s calculation neither analyzes the basis for any of the Medicaid payments for an Ery drug nor verifies whether Abbott’s reported prices did, in fact, impact the amount paid. (SOF ¶¶ 102-120.) Most state Medicaid agencies based their payments for multisource drugs on FULs or MACs (*id.* ¶¶ 71, 87-88), which most often were not calculated from any Abbott-reported price. (*Id.* ¶¶ 73-78, 89-92.) Duggan completely ignored this fact. (*Id.* ¶¶ 102-120.) Duggan simply assumed damages for every Medicaid claim for which the price that he says Medicaid should have paid (his “but-for” price) was lower than the actual Medicaid payment. (*Id.*) He admits that he did not at all determine or account for the basis for that payment (FUL, MAC, U&C, or other), whether the payment was based on a price that Abbott reported, or the clear federal and state policies to provide margins to pharmacies in order to maintain Medicaid patients’ access to the

⁴ Abbott is also filing a motion to exclude Dr. Duggan’s opinions. That motion more fully explains the flaws in Duggan’s methodology and calculations.

pharmaceuticals. (*Id.*) Second, to make matters worse, less than half of his calculated differences are even based on actual claims data. For that portion of his calculation, he used unsupported and unscientific extrapolations. (*Id.* ¶¶ 121-29.)

In addition, Ven-A-Care further inflates its damages number by including claims from Texas and California that Ven-A-Care has settled and released. (SOF ¶¶ 130-32.) The agreements to settle and dismiss claims that Abbott's pricing fraud harmed Texas and California Medicaid even provide that Ven-A-Care "covenant[s] not to sue or take any other civil or administrative action against Abbott based on the Covered Conduct." (*Id.* ¶ 130.)

STANDARD OF REVIEW

Summary judgment is appropriate where, as here, "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). An "issue is 'genuine' for purposes of summary judgment" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party, and a 'material fact' is one which might affect the outcome of the suit under the governing law." *Carcieri v. Norton*, 398 F.3d 22, 29 (1st Cir. 2005). Summary judgment "may be sought and entered on any part of a case." *Gore v. Trs. of Deerfield Acad.*, 385 F. Supp. 2d 65, 68 (D. Mass. 2005) (citing Fed. R. Civ. P. 56(b)).

ARGUMENT

I. THE COURT SHOULD GRANT SUMMARY JUDGMENT ON CLAIMS BARRED BY THE FCA'S STATUTE OF LIMITATIONS.

Ven-A-Care seeks liability and damages from January 1, 1994 through the present for all Medicaid claims for seventeen formulations (43 NDCs) of Ery. The FCA's six-year statute of

limitations, however, bars most of Ven-A-Care's claims. 31 U.S.C. § 3731(b)(1) (no civil action may be brought "more than 6 years after the date on which the violation . . . is committed").⁵

The relevant dates for this analysis are:

June 23, 1995	Ven-A-Care files first complaint against Abbott raising AWP claims. (This complaint was filed under seal in the S.D. Fla. and was not unsealed until 2006. Ven-A-Care made other AWP allegations against numerous other defendants.) (SOF ¶ 2.)
Aug.-Sept. 2000	Ven-A-Care researches Ery claims in public compendia and wholesaler price lists. (<i>Id.</i> ¶¶ 24, 27.)
February 15, 2001	Ven-A-Care adds Abbott and six formulations (13 NDCs) of Ery to Case No. 00CV10698 (D. Mass.) under seal. (<i>Id.</i> ¶¶ 8-9.)
February 1, 2002	Ven-A-Care amends under-seal complaint in 00-CV-10698 (D. Mass.) to allege fraudulent reporting of list price and damages to California Medicaid. (<i>Id.</i> ¶ 13.)
February 15, 2005	Ven-A-Care amends under-seal complaint in 00-CV-10698 (D. Mass.) to add national AWP claims and an additional five formulations (13 NDCs) of Ery. (<i>Id.</i> ¶ 15.)
August 30, 2007	Ven-A-Care files unsealed Complaint as Case No. 07-CV-11618-PBS and adds an additional six formulations (17 NDCs) of Ery. (<i>Id.</i> ¶ 19.)

The six-year statute of limitations bars Ven-A-Care's claims in two ways:

First, Ven-A-Care's claims expanding its case to AWP's and all forty-nine Medicaid States are barred prior to February 15, 1999 (six years before Ven-A-Care filed these expansive claims in its February 15, 2005 amended under-seal complaint).

Second, new claims about additional Ery drugs are limited to six years before Ven-A-Care first added the particular drug formulation to its pleadings.

The relation-back provisions under Federal Rule of Civil Procedure 15(c)(1) offer Ven-A-Care no relief from the six-year statute of limitations. Federal Rule 15(c)(1) permits an

⁵ The three-year tolling provision under § 3731(b)(2) does not apply to actions in which the Government has declined intervention. *See United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 723-25 (10th Cir. 2006).

amendment to a complaint to “relate back” to the earlier complaint only when (A) “the law that provides the applicable statute of limitations [in this case, the FCA] allows relation back” or (B) “the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out – or attempted to be set out – in the original pleading” and the defendant has received notice of the earlier claim. Fed. R. Civ. P. 15(c)(1)(A), (B). Neither part of Rule 15(c)(1) permits Ven-A-Care’s claims to relate back to earlier complaints.

A. Rule 15(c)(1)(A) Provides Ven-A-Care No Relief From The Statute Of Limitations.

Rule 15(c)(1)(A) allows relation back if the law that provides the statute of limitations (here, the FCA) permits relation back. The FCA, however, offers no relief to Ven-A-Care. The FCA, as recently amended by the Fraud Enforcement and Recovery Act of 2009 (“FERA”), 111 P.L. 21, now grants the Government, if it intervenes, relief from the statute of limitations.

Section 4 of the FERA, which took effect on May 20, 2009, amended 31 U.S.C. § 3731 of the FCA to add the following subsection (c):

If the Government elects to intervene and proceed with an action brought under 3730(b) [31 U.S.C. § 3730(b)], the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) [31 U.S.C. § 3730(b)], to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitation purposes, any such Government pleading shall relate back to the filing date of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

31 U.S.C. § 3731(c) (emphasis added); 111 P.L. 21, § 4(b). *See also* 111 P.L. 21, § 4(f)(2) (amendment applies to all cases pending on the date of enactment).

Notably, the amendment does not permit relation back when the government elects not to intervene. Congress’s silence is meaningful. The *expresio est exclusio alterius* cannon of

statutory construction rests on the presumption that Congress chooses purposefully to include one term while excluding another. *See United States v. Vidal-Reyes*, 562 F.3d 43, 53 (1st Cir. 2009); *In re 22 Main St.*, 262 F.3d 1, 10-11 (1st Cir. 2001). Had Congress wanted to allow relation back for relators, as it did for the Government, it would have done so; instead, it chose not to. Accordingly, the FCA's amendment does not apply to a relator litigating alone, and Rule 15(c)(1)(A) does not permit Ven-A-Care's new claims to relate back to any earlier filed, under-seal complaint.

Furthermore, the new provision allowing the Government's complaint to relate back requires that the new complaint's allegations arise from the same conduct, transaction or occurrence as the earlier pleading's allegations, which as shown in the next section is not the case here.

B. Rule 15(c)(1)(B) Provides Ven-A-Care No Relief From The Statute Of Limitations.

Rule 15(c)(1)(B) allows relation back only if the amendment asserts a claim that arose out of the conduct, transaction, or occurrence alleged in the earlier complaint and the defendant received notice of the earlier complaint. Fed. R. Civ. P. 15(c)(1)(B); *In re Pharm. Industry Average Wholesale Price Litig.*, 498 F. Supp. 2d at 398.

1. Abbott had no notice of earlier under-seal complaints.

Neither Ven-A-Care's expansive AWP-based claims nor its allegations about additional Ery drugs can relate back to earlier complaints under Rule 15(c)(1)(B) for the simple reason that Abbott received no notice of the earlier under-seal complaints. As this Court has recognized previously, Rule 15(c)(1)(B) requires notice of the complaint to which the plaintiff seek relation back. *In re Pharm. Industry Average Wholesale Price Litig.*, 498 F. Supp. 2d at 398. Indeed, "(as is well settled) the touchstone for relation back pursuant to [Rule 15(c)(1)(B)] is notice."

United States v. Baylor Univ. Med. Ctr., 469 F.3d 263, 270 (2d Cir. 2006); *see also Marsh v. Coleman Co.*, 774 F. Supp. 608, 612 (D. Kan. 1991) (citing *Schiavone v. Fortune*, 477 U.S. 21, 31 (1986)) (the “linchpin to Rule 15(c) is notice before the limitations period expires.”). Because Abbott did not have notice of any of the under-seal complaints, later allegations cannot relate back to the earlier under-seal complaints.

2. Ven-A-Care’s national AWP-based claims do not arise from the limited alleged misreporting of WAC.

In its February 15, 2005, amended, under-seal complaint, Ven-A-Care significantly expanded its claims from a limited case about the nine state Medicaid programs that used WACs or list prices (the eight “WAC states” plus California) to a large case about AWP and all forty-nine Medicaid States. (SOF ¶¶ 15-16.) According to Ven-A-Care’s expert’s calculations (and even assuming the full damages period and all NDCs alleged), the AWP claim alone expanded Ven-A-Care’s claimed damages from (according to Ven-A-Care’s calculations) \$2.3 million to \$15.5 million. Pursuant to the FCA’s six-year statute of limitations, the Court should grant summary judgment to Abbott on all AWP claims accruing prior to February 15, 1999. The AWP claims cannot relate back to the earlier, more limited claims under Rule 15(c)(1)(B).

Ven-A-Care’s national AWP claims did not arise out of the same conduct, transaction, or occurrence as Ven-A-Care’s significantly more narrow WAC claims for the eight WAC states, and therefore cannot relate back. Ven-A-Care’s first amended under seal-complaint made allegations regarding only the WAC prices for six Ery formulations and identified only eight state Medicaid programs that utilize WAC information and were allegedly defrauded by the WAC reporting. (SOF ¶¶ 9-12.) Ven-A-Care’s second amended under-seal complaint expanded the claims only to add the allegation that Abbott misreported its “direct prices” (in addition to its WACs) and thus, also allegedly defrauded the State of California. (*Id.* ¶ 13.) Notably, neither of

these complaints made any allegation of AWP-based fraud against Abbott. Ven-A-Care certainly was familiar with the concept: Ven-A-Care had been litigating AWP claims against Abbott on certain Abbott HPD products for an entire decade by the time Ven-A-Care added the AWP claims with respect to the Erys in this case in 2005; Ven-A-Care had been litigating AWP claims against other manufacturers; and Ven-A-Care had even included AWP allegations against the other defendants in the Massachusetts case, but did not do so against Abbott. Instead, Ven-A-Care specifically chose not to make any AWP allegations or to expand its allegations to all forty-nine state Medicaid programs until February 15, 2005. Ven-A-Care's own corporate representative testified that the reasons for the repeated amendments apparently "changed over time in our discussions with the attorneys," but Ven-A-Care specifically chose to limit its first amended under-seal complaint against Abbott to only "WAC fraud." (*Id.* ¶ 2-14.)

For relation-back purposes, claims are not "related" simply because they are part of the same "broad scheme." *In re Pharm. Industry Avg. Wholesale Price Litig.*, MDL No. 1456, 2007 WL 4287572, at *3 (D. Mass. Dec. 6, 2007); *see also O'Loughlin v. Nat'l R.R. Passenger Corp.*, 928 F.2d 24, 27 (1st Cir. 1991) (separate allegations of injury, on different days, due to "unsafe and inadequate working conditions" at the same workplace could not relate back); *United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys.*, 409 F. Supp. 2d 43, 45, 53 (D. Mass. 2006) (allegation of miscoding specific procedure did not relate back to claims of miscoding same procedure in a different year); *United States ex rel. Colunga v. Hercules Inc.*, No. 89-CV-954, 1998 WL 310481, at *1-2 (D. Utah Mar. 6, 1998) (false claims allegations related to "improper alodining" of Titan IV and other missile systems did not relate back to allegations of "improper alodining" of Pershing II missile systems, as "[d]ifferent rocket systems became the subject of the complaint"); *In re Bausch & Lomb, Inc. Sec. Litig.*, 941 F. Supp. 1352, 1366 (W.D.N.Y. 1996) (rejecting relation back based on notion that pleadings were part of the "same

general scheme”). Where, as here, new claims “expand or modify facts asserted in the earlier pleading,” they will not “relate back.” *United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys., Inc.*, 409 F. Supp. 2d 43, 53 (D. Mass. 2006). Nor will an amended complaint relate back where it “attempts to introduce a new legal theory based on facts different from those underlying . . . timely claims.” *La. Wholesale Drug Co. v. Biovail Corp.*, 437 F. Supp. 2d 79, 86 (D.D.C. 2006), *aff’d by Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857 (D.C. Cir. 2008) (quoting *United States v. Hicks*, 283 F.3d 380, 388 (D.C. Cir. 2002)).

Ven-A-Care’s new allegations about AWP raised new facts and new legal issues. Most significant, the AWP claims expanded the case from nine to forty-nine state Medicaid programs, involving millions of different Medicaid claims for payment and different States’ different policies and procedures used to calculate those payments. In addition, while Abbott reported WACs and list prices for the Ery drugs, the pricing compendia actually calculated the AWPs for them. (*Id.* ¶ 62.) The fact, or any dispute about this fact, raises many legal and factual issues that are not present in a case involving only WAC and list price reporting. New claims about entirely different Medicaid payments based on a different pricing term expanded to the entire country rather than just nine States do not relate back to earlier, narrower complaints.

Accordingly, pursuant to Rule 15(c)(1)(B), Ven-A-Care’s AWP claims raised for the first time in the 2005 amended complaint cannot relate back to earlier under-seal complaints, and the statute of limitations bars AWP-based claims prior to February 15, 1999 (six years before they were first raised).

3. Ven-A-Care’s new allegations about additional Ery drugs do not arise from allegations about different Ery drugs.

Between filing its initial complaint in 2001 and filing its unsealed Complaint in 2007, Ven-A-Care kept adding claims relating to additional Ery drugs. Its original complaint against

Abbott in Case No. 00-CV-10698 named six Ery drugs (thirteen NDCs). (SOF ¶ 9.) The 2005 amendment added five different drug formulations (thirteen NDCs). (*Id.* ¶ 17.) The unsealed Complaint in 2007 added yet another six (seventeen NDCs). (*Id.* ¶ 20.) As this Court has ruled previously, allegations about Medicaid fraud with respect to one drug do not arise from the same conduct, transaction, or occurrence as allegations about Medicaid fraud with respect to different drugs, and therefore the later allegations do not relate back to the earlier pleading. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 498 F. Supp. 2d 402, 405 (D. Mass. 2007).

The different Ery formulations are different drugs that use the same antibiotic salt compounds. (SOF ¶ 52.) They are prescribed for different purposes and to different types of patients, and compete with different drugs. (*Id.*) For example, Pediazole Suspension (named in the 2005 complaint) is prescribed for, and used by, only pediatric patients. It is by no means interchangeable with Ery-Tab, for example. (*Id.*) In addition, they have different prices and different spreads. Allegations about one Ery formulation simply cannot be considered arising from the same conduct, transaction, or occurrence as allegations about a different Ery drug.

Even Ven-A-Care has treated the different Ery formulations as different drugs. Ven-A-Care's explanation for adding additional formulations is simply that Ven-A-Care started with the drugs with the biggest spreads and that along the way it decided to add those drugs that "may or may not have quite as big a spread." (SOF ¶ 24.) Ven-A-Care does not claim, for example, that it merely neglected to add an additional NDC of a formulation. Ven-A-Care's explanation, if anything, just confirms that the Ery formulations should be treated as different drugs and that allegations about additional formulations cannot relate back to the initial under-seal complaint against Abbott.

For these reasons, Ven-A-Care's claims regarding one Ery formulation cannot relate back to earlier claims about other formulations, and the Court should enter summary judgment applying the six-year statute of limitations to limit Ven-A-Care's claims about each Ery drug to six years before Ven-A-Care first added the drug to its pleadings.

II. KNOWLEDGE OF THE ALLEGED FRAUD, INCLUDING THE EXTENT THAT PUBLISHED ERY PRICES EXCEEDED ACTUAL TRANSACTION PRICES, PRECLUDES DAMAGES ANY LATER THAN FEBRUARY 2001 WHEN VEN-A-CARE FILED ITS COMPLAINT.

Not only does the statute of limitations cut off Ven-A-Care's claims going back in time, but the Government's knowledge of Ven-A-Care's specific allegations bars claims after Ven-A-Care apprised the Government of the allegations in 2001. If necessary, Abbott will prove at trial that the overwhelming public and government knowledge about alleged price inflation generally and the spreads on the Ery drugs specifically – based on Government and media reports about “spreads” on Erys (SOF ¶¶ 25-41) and Abbott's own reporting of AMPs on the Erys (*Id.* ¶ 61) – precludes damages well before 2001. There can be no dispute, however, that by February 2001 the Government was fully knowledgeable about the alleged fraud including the price spreads. By then, Ven-A-Care, as required by 31 U.S.C. § 3730(b)(2), had disclosed to the Government the facts supporting its allegations, including the same pricing database (Econolink) that Ven-A-Care used then and later to discover the alleged disparities between the Erys' transactional and published prices (SOF ¶ 50), and the February 15, 2001 under-seal complaint, including the specific price information alleged therein. (*Id.* ¶ 19). Moreover, these disclosures to the Government were in the context of many other price-spread complaints and, as this Court has found, a “perfect storm” of knowledge about price spreads and manufacturers' conduct relating to them. Yet, armed with this knowledge, the Government continued to approve and authorize

payment for providers' claims for Ery drugs. The Government's knowledge of the specific facts underlying the allegations in the case preclude damages at least from February 2001 forward.⁶

For actual damages, the FCA adds a heightened causation element. 31 U.S.C. § 3729(a)(1) (Government may only recover actual damages that the "Government sustains *because of* the act of that person.") (emphasis added). Accordingly, under the statute, the Government cannot recover actual damages for an allegedly false claim unless it can plead and prove damages actually *caused by* the false claim. *See, e.g., United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995); *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (distinguishing FCA cases where the Government is "induc[ed]. . . to pay out funds" from cases with only statutory penalties).

This reading of the Act's plain text is consistent with "common-law tort causation concepts," which this Court has previously examined to assess FCA causation. *United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651-PBS, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003); *accord United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (citing, with approval, courts "borrow[ing] traditional principles of tort law to analyze causation for damages under the FCA"). A party generally may not seek to recover damages in tort that it voluntarily elects to suffer. The seminal opinion of *Thompson v. Libby*, 31 N.W. 52, 53 (Minn. 1886), expresses this principle well:

⁶ Knowledge also negates two other FCA elements: (1) the claim's falsity; and (2) the defendant's state of mind (scienter). *In re Pharm. Industry Average Wholesale Price Litig.*, 254 F.R.D. 35, 41 (D. Mass. 2008); *see also United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 288 (4th Cir. 2002) (joining the 2nd, 7th, 9th and 10th Circuit Courts in recognizing "that prior government knowledge of an allegedly false claim can negate the scienter required for an FCA violation."); *United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999) ("The government's knowledge [of an allegedly false claim] effectively negates the fraud or falsity required by the FCA."); *United States ex rel. Butler v. Hughes Helicopters*, 71 F.3d 321, 327 (9th Cir. 1995) (finding that when government representatives were made aware of alleged discrepancies, a contractor could not have "knowingly" submitted a false claim). "Since the crux of an FCA violation is intentionally deceiving the government, no violation exists where the government has not been deceived." *United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 988 (E.D. Wis. 1998). Because Abbott believes that the elements are intertwined with disputed questions of fact, they are not the subject of this motion.

[T]o allow a person who has discovered the fraud while the contract is still wholly executory to go on and execute it, and then sue for the fraud, looks very much like permitting him to speculate upon the fraud of the other party. It is virtually to allow a man to recover for self-inflicted injuries.⁷

If the Government pays a claim *despite knowing of the claim's falsity*, the Government cannot say that it was damaged “by reason of” (i.e., “because of”) that falsity.

Courts apply this standard rigorously because the FCA provides for automatic treble damages, so the damages provisions are considered punitive in nature. *Vermont Agency of Natural Resources v. United States*, 529 U.S. 765, 784-85 (2000). Accordingly, courts apply a proximate causation standard to “narrow, rather than enlarge, the field of actions for which FCA liability may be imposed.” *Regence Bluecross Blueshield of Utah*, 472 F.3d at 715 n.17; *see also United States ex rel. Fago v. M&T Mortgage Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007) (“Plaintiff must go beyond a “but for” showing and demonstrate that the false statements in this case were the proximate cause of the Government’s actual damages.”). Under this standard, damages must not only be foreseeable, but must also have a sufficiently close causal connection to a defendant’s conduct. *See Parke-Davis*, 2003 WL 22048255, at *4-*5. In other words, where the Government knew of allegedly false information, yet made a financial commitment or paid out nonetheless, there can be no recovery of actual damages.⁸

⁷ *Accord, e.g., Thor Power Tool Co. v. Weintraub*, 791 F.2d 579, 585 (7th Cir. 1986) (“[g]enerally, a defrauded party cannot recover damages for the period after the victim discovers the fraud”); *Slotkin v. Citizens Cas. Co. of N.Y.*, 614 F.2d 301, 313 (2d Cir. 1979) (noting that “[t]his rule prevents a plaintiff from recovering damages for ‘self inflicted’ injury”); *Sanitoy, Inc. v. Shapiro*, 705 F. Supp. 152, 156 (S.D.N.Y. 1989) (“Many cases have held that if a plaintiff continues to deal with a defendant after discovering the truth of the defendant’s misrepresentations, the plaintiff waives any fraud claim for damages arising subsequent to the discovery.”) (collecting authorities).

⁸ *See, e.g., United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (“It may be, as the district court observed, that no damages were suffered when officers of the United States knowledgeably decided to proceed with the contract” despite its false claims); *United States ex rel. Herbert v. Nat’l Academy of Sciences*, Civ. A. No. 90-2568, 1992 WL 247587 (D.D.C. Sept. 15, 1992) (“The U.S. consented to [the alleged fraud] at a time when it actually knew of Plaintiff’s claim, and was on notice of the Plaintiff’s allegations of fraud.”); Neal J. Wilson, *The Government Knowledge “Defense” to Civil False Claims Actions*, 24 Pub. Cont. L.J. 43, 61 (1994) (“Where the Government has knowledge of allegedly false or fraudulent information submitted in

For instance, in *United States ex rel. Butler v. Hughes Helicopter Co.*, No. CV 89-5760, 1993 WL 841192 (C.D. Cal. Aug. 25, 1993), *aff'd on other grounds* 71 F.3d 321 (9th Cir. 1995), the court held that, even if the defendant were liable under the FCA, “actual damages (in contrast to civil penalties) could not have been found as a matter of law” where the Government “was aware of the deficiencies” that formed the basis of the FCA suit, yet “nevertheless elected to proceed” and execute its contract with Defendant. *Id.* at *16. In such a situation, the Court held the “government knew what it was getting . . . and it got what it paid for,” and thus there was no “causal connection” between the false statements and payment of the false claim. *Id.*

Likewise, in *United States v. Southland Management Corp.*, 95 F. Supp. 2d 629, 642-43 (S.D. Miss. 2000), *aff'd on other grounds* 326 F.3d 669 (5th Cir. 2003) (en banc), applicable regulations of the Department of Housing and Urban Development conditioned payment of Section 8 housing vouchers on management’s certification that its properties were in a “decent, safe, and sanitary” condition. *Id.* at 631. The Government brought an FCA suit against a property management company that falsely made this certification; however, it was established that HUD paid Defendant’s vouchers with knowledge about the true condition of the properties and the falsity of the certifications. *Id.* Noting that “a statement or claim can be material, *i.e.*, *capable of* influencing action, without actually inducing reliance or causing damage,” the district court held “that the Government was not, in fact, damaged by defendants’ certifications” when it paid the housing vouchers despite knowing about the false certifications. *Id.* at 642-43. The court in *Southland* ultimately found that Defendants were not liable under the FCA, even for

(continued...)

support of a demand for payment, and yet still makes the payment, there would appear to be a break in the causal link between the false or fraudulent claim and the asserted Government injury. In such a situation, the Government’s act of making payments despite knowledge of the defendant’s alleged wrongdoing makes it difficult to articulate exactly how the Government has been damaged.”).

statutory penalties.

In this case, the Government became aware of the allegedly fraudulent conduct relating to the Ery drugs no later than February 2001, after Ven-A-Care had provided the Government copies of the Econolink data, the Section 3730(b)(2) disclosure and the under-seal complaint. That the Government has continued to pay the claims at issue here despite knowing of Abbott's allegedly inflated prices for the Ery drugs precludes a finding of damages. These self-inflicted damages were not "sustain[ed] because of" the allegedly false claims within the meaning of the FCA. Rather, payments were made with full knowledge of the alleged fraud, and indeed, after 2001, with the very complaint containing the FCA allegations in this suit *filed and in hand*. The FCA does not permit actual damages in such a situation; to allow otherwise would "permit plaintiffs who know of the defendant's pattern of activity simply to wait, 'sleeping on their rights,' as the pattern continues and treble damages accumulate, perhaps bringing suit only long after the 'memories of witnesses have faded or evidence is lost.'" *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 186-88 (1997) (declining to interpret treble-damages statute to permit this consequence).

III. THE COURT SHOULD GRANT SUMMARY JUDGMENT TO ABBOTT ON COUNT I BECAUSE THE UNDISPUTED FACTS DEMONSTRATE THAT ABBOTT DID NOT VIOLATE THE ANTI-KICKBACK STATUTE.

In Count I of the Complaint, Ven-A-Care alleges that Abbott, in violation of 31 U.S.C. 3729(a)(1), caused false and fraudulent claims to be submitted by "knowingly us[ing] the spread as an unlawful inducement in violation of the federal anti-kickback statute." (SOF ¶ 22.) First, this allegation is insufficient to state a violation of Section 3729(a)(1) or the anti-kickback statute. Ven-a-Care does not allege, as it must to state a claim under Section 3729(a)(1) or the anti-kickback statute, that Abbott actually caused a provider to submit a false claim or that Abbott made a direct payment or remuneration to a provider. Second, Ven-A-Care has failed to present

evidence to support its inadequate allegation that Abbott affirmatively marketed the spread to providers or even that an alleged price spread caused a pharmacy to purchase and make any Medicaid claim on any Ery drug.

Section 3729(a)(1) applies if a defendant “knowingly causes to be presented ... a false or fraudulent claim” to the United States government. *See* 31 U.S.C. § 3729(a)(1). Here, the law is clear. A defendant cannot have “caused” a claim to be submitted unless the defendant affirmatively instructed another party to submit the claim or delegated its power to submit a claim to the other party. *United States ex rel. Shaver v. Lucas Western Corp.*, 237 F.3d 932, 933-34 (8th Cir. 2001) (holding that defendant employer did not cause relator to submit a false claim by failing to pay workers’ compensation medical bills because defendant did not instruct the relator to submit the claim and did not affirmatively act to cause the claim to be submitted); *United States ex rel. Kinney v. Hennepin County Med. Ctr.*, No. 97-1680, 2001 U.S. Dist. LEXIS 25475, at *34-*35 (D. Minn. 2002) (holding that defendant’s fraudulent certification to Medicare and Medicaid of hospital’s ambulance services as “medically necessary” did not cause claim to be presented because hospitals billings department coded claims without instruction from defendant). Ven-A-Care certainly cannot meet this standard.

Moreover, a violation of the anti-kickback statute requires an “offer” or “payment” of “remuneration.” *See In re Pharm. Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 24-25 (D. Mass. 2007). Subsection (b) of the federal anti-kickback statute entitled “Illegal Remuneration,” imposes liability on a provider who receives an illegal “kickback” “in return for purchasing . . . any good . . . or item for which payment may be made in whole or in part under a Federal health care program.” *See* 42 U.S.C. § 1320a-7b(b)(1)(B). A “kickback” means “the transfer *back to* one having control of the original payment.” *U.S. v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980) (emphasis added).

Here, the original payment was a purchase by pharmacies of Abbott drugs; a “kickback” would require a transfer back to pharmacies from *Abbott*. Ven-A-Care, however, does not allege that Abbott paid anything back to pharmacies in exchange for them dispensing the Ery drugs. Instead, Ven-A-Care seems to be claiming that the “illegal remuneration” came from the Government as a result of Abbott’s alleged fraudulent published prices. That, however, is not an “offer” or “pay[ment]” under the anti-kickback statute. *See* 42 U.S.C. § 1320a-7b(b)(2).

Moreover, even if an indirect remuneration through the Government could support a kickback claim, the alleged fraud could not even support that theory. Where, as with the Ery drugs, a FUL or MAC is in place, there is no incentive for a manufacturer to raise AWP or for a pharmacy to purchase a drug with a higher AWP because the FUL or the MAC cap payment. Ven-A-Care’s theory of remuneration is legally insufficient and factually nonsensical. Indeed, in its decision on Abbott’s motion to dismiss the complaint in the DOJ case, this Court concluded that reporting fraudulent prices, without more (i.e., without the direct inducement, which is impossible for generic drugs paid based off a FUL or MAC), is not an offer or payment of remuneration under the anti-kickback statute. *See In re Pharm. Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d at 24-25 (“[Abbott] has the better argument that mere publication of a false AWP, without more, does not constitute an offer of remuneration where reimbursement is based on a median of AWP, as it is with Abbott’s multi-source drugs.”).

On top of that, Ven-A-Care has no evidence to support its legally deficient claim that Abbott actively marketed the spread or that Abbott’s pricing or reporting caused any provider to purchase, dispense, and make a Medicaid claim on an Abbott Ery drug. Ven-A-Care has not even offered any evidence that Abbott’s spreads were larger than any competitor’s, that any

provider dispensed and submitted a claim for an Abbott Ery instead of a competing product, or that Abbott's pricing or reporting affected Abbott's market share in any way, shape or form.⁹

After months of discovery, including thousands of documents and numerous depositions, Ven-A-Care cannot point to any evidence that Abbott provided kickbacks to providers to purchase the Ery drugs or affirmatively marketed the spread. Instead, the evidence shows that Ven-A-Care's claim that Abbott violated the anti-kickback statute rests solely on the allegation that Abbott's published prices for the multiple-source Ery drugs were false, which this Court has already ruled is insufficient to state a violation of the anti-kickback statute. Accordingly, the Court should enter summary judgment for Abbott on Count I.

IV. VEN-A-CARE IS NOT ENTITLED TO DAMAGES ON CLAIMS FOR WHICH THE MEDICAID PAYMENT WAS NOT BASED ON A PRICE REPORTED FOR AN ABBOTT ERY.

Actual damages under the FCA cannot be recovered when they are “remote,” “speculative,” “hypothetical,” or otherwise “not within the realm of reasonable certainty.” *U.S. ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 55 (D.D.C. 2005). Courts should be especially exacting with this standard where, as here, the statute at issue provides for trebling of actual damages. *See Euromodas v. Zanella*, 368 F.3d 11, 17 n.5 (1st Cir. 2004) (noting that courts have “limit[ed] the inferences [that may be drawn] from ambiguous evidence” in antitrust cases because they “expose[] a defendant to treble damages”); Breckinridge L. Wilcox & Jefferson M. Gray, *Extrapolation of Damages and Penalties in Fraud Cases: A Slippery Slope in FCA Actions*, *Business Crimes Bulletin* (Dec. 2000) (“[T]he FCA’s

⁹ The Court’s ruling in *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754 at *12-13 (D. Mass. 2003), provides no help to Ven-A-Care. Whereas the relator in *Franklin* offered circumstantial and direct evidence that the defendant’s marketing of off-label drug use was a “substantial factor” that directly caused doctors to write prescriptions for off-label uses, Ven-A-Care has offered no evidence that Abbott in fact influenced the providers to submit claims on Erys. *See id.* at *13. Instead, Ven-A-Care rests only on the theory that the spread marketed itself. A plaintiff cannot avoid summary judgment, however, with theory alone. *Scott v. Harris*, 550 U.S. 372, 381, 127 S.Ct. 1769, 1776 (2007).

provisions for multiple damages and penalties mean that the financial impact of any claims erroneously treated as improper under the extrapolation will be greatly magnified.”).

Here, Ven-A-Care has failed to adduce any evidence of actual damages for the allegedly false claims at issue. Without such evidence, there is no reason to “needlessly prolong[] the litigation, only to [permit Ven-A-Care to] lose at trial due to the same dearth of admissible evidence.” *Maier-Schule GMC, Inc. v. General Motors Corp.*, 154 F.R.D. 47, 59 (W.D.N.Y. 1994). Rather, summary judgment on actual damages should be granted to Abbott now. *See Fed. R. Civ. P. 56(b) & (d); Masso v. United Parcel Serv. of Am., Inc.*, 884 F. Supp. 610, 620 n.8 (D. Mass. 1995) (“Defendants may, of course, seek summary judgment, in whole or in part, to the extent that [plaintiff] cannot recover damages.”); *Bonacorso Const. v. Master Builders, Inc.*, No. 87-1827, 1991 WL 72796, at *9-10 (D. Mass. Apr. 24, 1991) (granting summary judgment as to damages).¹⁰

Ven-A-Care’s damages theory for these multiple-source drugs assumes, but fails to prove, a causal link between the publication of an allegedly false price (AWPs and prices reported to compendia) on the one hand and the Government’s injury on the other (i.e., that the claim was paid based on the allegedly false price). To the extent that Medicaid did not pay based on a compendia-reported price for the Abbott Erys—as is true for most of the payments at issue in this case where a FUL, MAC, U&C, or some other basis was used—Ven-A-Care’s theory is invalid.

Neither Ven-A-Care nor its expert (Dr. Duggan) even tried to address the issues raised by

¹⁰ Summary judgment on damages for Abbott on these claims is appropriate even if issues of fact may exist for a jury to consider as to liability. *See Bonacorso*, 1991 WL 72796, at *9-10 (granting summary judgment to plaintiff on liability and defendant on damages); *Maier-Schule GMC*, 154 F.R.D. at 52-61 (“[T]his Court has found numerous cases where a court granted a defendant summary judgment on some or all of plaintiff’s claims for damages despite the fact that the court determined that the plaintiff presented otherwise meritorious claims.”) (citing cases).

MAC, FUL, or U&C-based Medicaid payments. They merely calculated “differences” for nearly every claim in the case, regardless of whether the payment was based on a reported price for an Abbott Ery. *See* 31 U.S.C. § 3729(a) (allowing “damages which the Government sustains *because of* the act of” the defendant) (emphasis added). Without Dr. Duggan’s flawed testimony, which should be excluded,¹¹ the Government has no evidence to support these damages claims.

This Court has consistently ruled in AWP litigation that, to recover damages for claims involving multi-source drugs, plaintiffs must show that the claims were in fact paid based on a published price for the drug at issue. In the California AWP litigation, for example, the Court dismissed the complaint “as it relates to the drugs reimbursed on a MAIC methodology” (California’s state MAC) because there was no causal link between the MAIC prices and the allegedly false prices reported by the defendants. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 180 (D. Mass. 2007); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 91 (D. Mass. 2005) (holding, for third-party payors in the non-Medicare Part B context, that “generics will be considered only to the extent the price in the contract between the TPP and physician is expressly predicated on AWP”). These rulings, and their rationale, require that damages for many of the claims at issue be adjudicated in Abbott’s favor at this stage.

First, many of the Medicaid claims were paid based on a state MAC. (SOF ¶ 88.) Although Ven-A-Care did not bother to determine whether the claims at issue were paid based on a MAC, a FUL, an EAC, a U&C or some other basis (*id.* ¶ 109-10, 116), discovery of some of the state Medicaid programs showed that at least twenty-two of them used MACs on the Ery

¹¹ Concurrent with this motion, Abbott is filing a motion to exclude Dr. Duggan’s testimony. Even if Dr. Duggan’s work were admissible, it could not establish a genuine issue of material fact as to damages for these claims. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993) (noting that summary judgment remains available as one “means of attacking shaky but admissible evidence”).

drugs (*id.* ¶ 88). The Government offers no evidence concerning how, if at all, Abbott’s allegedly inflated prices impacted the MAC levels set by the States. Indeed, the MAC pricing instituted by many states was not affected at all by compendia prices. (*Id.* ¶¶ 89-92) Yet, Ven-A-Care’s damage model includes damages on claims paid based on these MACs regardless of whether the MAC was based on a compendia price for an Abbott Ery drug and, therefore, dramatically inflates damages. Remarkably, Ven-A-Care relied on Myers & Stauffer to determine how the state Medicaid programs reimbursed drugs, but Ven-A-Care did not ask that firm to identify which states implemented MACs on the Ery NDC (and, if so, when) or how those MAC levels were determined. (*Id.* ¶¶ 115.)

To permit the Government to characterize as an illegal “overpayment” any difference between a state MAC and a revised AWP or WAC-based allowable amount—particularly where there is no link between the reported price and the MAC—would overturn state policy on what payment levels were appropriate and fair under the circumstances. Extensive record evidence makes clear that MAC pricing (and pricing in general) was influenced by policy determinations and a give-and-take with providers to come up with levels that were fair under the circumstances. (SOF ¶¶ 91-92.) The Government’s approach completely ignores that many States’ MACs intentionally provided margins to providers. For example, the Myers & Stauffer analysis prepared for this litigation asserts as follows in regard to Minnesota’s approach to establishing MACs:

SMACs are based on an informal survey of a few retail pharmacies that have agreed to share their costs. *The State tries to include an average profit of about \$7.00 for each prescription using SMAC.* This \$7 includes the \$3.65 dispensing fee. . . .

(*Id.* ¶ 92.) (emphasis added). North Carolina set its MAC levels at the providers actual acquisition cost plus 20 percent, intentionally allowing for a profit margin. Wyoming set its

MAC levels at the providers actual acquisition cost plus 40 percent in order to “ensure access to [providers]” (*Id.*) Yet Duggan admitted that he did not consider such evidence. (*Id.*)

Second, similar issues exist with respect to FULs. During the time period relevant to the claims at issue here, the FUL was supposed to be set by CMS at 150% of the single lowest price reported in the compendia among the generically equivalent multi-source drugs, an amount that may have had nothing to do with the published prices for Abbott’s Erys. *See* 42 C.F.R.

§ 447.332 (2007).¹² Sue Gaston, the CMS employee responsible for setting FULs from April 1991 through February 2003, testified, however, that CMS did not necessarily always implement a FUL at 150% of the lowest published price and that other policy considerations were at play. (SOF ¶ 73-78.) For example, CMS employees would try to determine the availability of the lowest published price prior to implementing it. (*Id.* ¶ 76.) Based on policy considerations and discussions with the pharmacy community, higher prices often were used to set the FULs. (*Id.* ¶ 77-78.) Again, Ven-A-Care’s damages ignore the use of FULs and, thus, inflates damages by including alleged “overpayments” due to any difference between a FUL and a revised AWP or WAC-based allowable amount.

Finally, Dr. Duggan’s work shows that a considerable portion of the remaining Medicaid claims at issue were reimbursed based on U&C. (SOF ¶ 106.) As with MACs and FULs, it is undisputed that Ven-A-Care’s model includes damages on claims paid based on provider’s submitted U&Cs. (*Id.*) Ven-A-Care has made no effort to separate out such claims from its

¹² In 2006, Congress passed the Deficit Reduction Act (“DRA”), which amended the FUL statute, 42 U.S.C. § 1396r-8. This amendment required CMS to “substitute 250 percent of the average manufacturer price (as computer without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.” Pub. L. No. 109-171 § 6001, 120 Stat. 4, 54-55 (2006). On July 17, 2007, CMS published a final rule implementing the FUL formula established by the DRA. Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142 (July 17, 2007). That regulation, however, has not gone into effect because of litigation brought by various pharmacist groups to prevent its implementation. *See Nat’l Ass’n of Chain Drug Stores v. U.S. Dep’t of Health & Human Servs.*, No. 07-cv-02017-RCL (D.D.C. Nov. 7, 2007.) (SOF ¶¶ 80-86)

damages calculation, even though payment on those claims had no connection to Abbott's reported prices.

V. VEN-A-CARE IS NOT ENTITLED TO DAMAGES BASED ON FLAWED AND INADMISSIBLE EXTRAPOLATIONS.

Ven-A-Care does not have or did not use the detailed Medicaid claims data necessary to show how thirty-four State Medicaid programs actually determined the payment amounts for the allegedly false claims at issue. (SOF ¶¶ 104-08.) Even as to the fifteen State Medicaid programs that produced some detailed claims data, there are significant time periods for which those States' claims data are not available. (*Id.*) The Government is responsible for failing to have the States maintain the data. *United Medical Supply Co v. U.S.*, 77 Fed. Cl. 257, 275 (Fed. Cl. 2007) (sanction imposed prohibiting United States from introducing its own expert testimony regarding certain "gaps" in evidence created by Government's spoliation of evidence.) The unavailability of the evidence necessary to prove and quantify this causal link warrants summary judgment as to damages on all claims for which Ven-A-Care does not have or did not use the underlying data.

Ven-A-Care cannot use an expert opinion to paper over this glaring deficiency. Ven-A-Care asked Dr. Duggan to extrapolate data from fifteen States to cover the massive gaps in its data, both within the group of States for which some data was used, and across States for which no data was used. (SOF ¶¶ 121-28.) Abbott has moved to exclude all testimony from Dr. Duggan concerning any aspect of his damages computation that relies upon such extrapolation because, as set out in more detail in that motion (filed herewith), Dr. Duggan's extrapolated "differences" are inconsistent with basic statistical standards, subject to clear selection bias, and demonstrably unreliable.

Without this expert testimony, Ven-A-Care has no evidence at all to prove causation and

damages for the many allegedly false claims where Ven-A-Care lacks actual data. *See, e.g., Albert v. Warner-Lambert Co.*, 234 F. Supp. 2d 101, 106-07 (D. Mass. 2002) (excluding expert testimony on damages and granting defendant's motion for summary judgment). *See also, Norfolk Southern Corp. v. Chevron U.S.A., Inc.*, 279 F. Supp. 2d 1250, 1268-79 (M.D. Fl. 2003), *rev'd on other grounds*, 371 F.3d 1285 (11th Cir. 2004); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003). Even with the testimony, no reasonable jury could conclude that Ven-A-Care has proved that the damages were sustained "because of" Abbott's acts. *See* 31 U.S.C. § 3729(a); *see also Daubert*, 509 U.S. at 596; *see, e.g., Miller v. Mandrin Homes, Ltd.*, 305 Fed. App'x. 976, 979-80 (4th Cir. 2009) (concluding that even if expert's conclusions were admissible, they would not defeat summary judgment). Summary judgment on these extrapolated claims is required.

VI. VEN-A-CARE ALSO IMPROPERLY INCLUDES CLAIMS THAT IT HAS SETTLED.

Duggan's calculations are even further inflated because he included claims for Texas and California even though Ven-A-Care has settled and agreed not to sue with respect to those claims. (SOF ¶ 128-130.) There is no factual dispute about the settlement agreements. Ven-A-Care has settled, released, and agreed not to sue on these claims. (*Id.* ¶ 128-130.) The Court should grant summary judgment to Abbott on the Texas and California claims and order Ven-A-Care to remove them from Ven-A-Care's calculation of damages and any calculation of "false or fraudulent claims" that Ven-A-Care may present at trial.

CONCLUSION

For the reasons stated above, this Court should grant Abbott's motion and enter summary judgment for Abbott on the AWP-based claims accruing before February 15, 1999, on claims with respect to each Ery drug accruing earlier than six years before the drug was added to the

case, on any alleged damages after February 15, 2001, on Count I, on Ven-A-Care's flawed damages claims, and on all claims relating to Texas and California Medicaid.

Dated: August 28, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A. Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton